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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,441	07/29/2003	Alastair Hodges	LFSCAN.079C1C1	8256

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EXAMINER	
OLSEN, KAJ K	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 09/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,441	HODGES ET AL.	
	Examiner	Art Unit	
	Kaj K. Olsen	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Double Patenting

1. The examiner has withdrawn the outstanding double patenting rejection in view of the filed terminal disclaimer, which has been approved.

Claim Rejections - 35 USC § 112

2. The examiner has withdrawn the outstanding 112 rejections in view of the arguments for claim 13 and the amendment to claim 14.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-7, 10-13, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al (J. Electroanal. Chem., 178 (1984), pp. 69-86) in view of Maley et al (USP 5,529,676).

6. With respect to claim 1, Allen discloses a coated metal electrode comprising numerous different sulfur-containing moieties for said coating. See p. 72 for a discussion of the metal electrode and table 1 for a listing of the moieties being relied on. Allen does not explicitly disclose overcoating this coating with a surfactant. Maley teaches in an alternate coated electrode that subsequent treatment of the electrode with a surfactant improves the storage life and the wetting properties of the electrode. See col. 30, l. 56 through col. 31, l. 8 and fig. 22 and 23. Said subsequent treatment of the electrode with surfactant would read on the specified "overcoating" giving the claim language its broadest reasonable interpretation. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Maley for the electrode of Allen in order to improve the storage life and wetting properties of the electrode.

7. With respect to claims 2-4, see structures 2, 19 and 46 from fig. 3.

8. With respect to claim 5, see elements 28-30 of Table 1.

9. With respect to claims 6 and 7, see structures 4, 10a, 14a-16a from fig. 3.

10. With respect to claims 10 and 11, see structure 4 from fig. 3.

11. With respect to claim 12, this only further limits claim 11 when alkyl groups are chosen from claim 11. Because Allen teaches the use of aromatic groups (see above), Allen reads on claim 12 when aromatic groups are chosen from claim 11.

12. With respect to claim 13, see elements 7 and 28 from table 1.

13. With respect to claim 18, Allen teaches contacting a metal electrode with a sulfur containing moiety (p. 72), but doesn't teach contacting the electrode with a surfactant. As discussed above, Maley teaches in an alternate coated electrode that subsequent treatment of the electrode with a surfactant improves the storage life and wetting properties of the electrode. See col. 30, l. 56 through col. 31, l. 8 and fig. 22 and 23. Said subsequent treatment of the electrode with surfactant would read on the specified "overcoating" giving the claim language its broadest reasonable interpretation. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Maley for the electrode of Allen in order to improve the storage life and wetting properties of the electrode.

14. With respect to claim 19 (those limitations not covered above), Allen utilizes the electrode as a measurement means for determining the presence of cytochrome c in the solution (see abstract, pp. 72-75 and fig. 1). This would read on the claimed "obtain a measurement indicative of a presence of an analyte in the sample".

15. Claims 1, 2 and 6-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlereth et al (Electroanalysis 1995, 7 (1), pp. 46-54) in view of Maley et al (USP 5,529,676).

16. With respect to claim 1, Schlerich discloses a coated metal electrode were the metal electrode comprising a coating of a sulfur containing moiety comprising cysteine. See Abstract and Scheme 1. Schlerich does not explicitly disclose the use of an overcoating of surfactant. Maley teaches in an alternate coated electrode that subsequent treatment of the electrode with a surfactant improves the storage life and wetting properties of the electrode. See col. 30, l. 56 through col. 31, l. 8 and fig. 22 and 23. Said subsequent treatment of the electrode with surfactant would read on the specified "overcoating" giving the claim language its broadest

reasonable interpretation. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Maley for the electrode of Schlereth in order to improve the storage life and wetting properties of the electrode.

17. With respect to claim 2, see scheme 1 of Schlereth.

18. With respect to claims 6-9 and 13, see the cysteine of scheme 1.

19. With respect to claims 10 and 11, scheme 1 also shows examples of alkyl and aromatic spacers.

20. With respect to claim 12, this only further limits claim 11 when alkyl groups are chosen from claim 11. Because Schlereth teaches the use of aromatic groups (see above), Allen reads on claim 12 when aromatic groups are chosen from claim 11.

21. With respect to claims 14-17, cysteine is inherently a stereospecific molecule. Although Schlereth does not specify which form of cysteine is present, Schlereth discusses no criticality as to the choice of isomer is present and one possessing ordinary skill in the art would have been motivated to utilize either the D or L isomer (or both) because they would all provide the desired monolayer for the electrode.

22. With respect to claim 18, Schlereth teaches contacting a metal electrode with a sulfur containing moiety (see section 2.1.1), but doesn't teach contacting the electrode with a surfactant. As discussed above, Maley teaches in an alternate coated electrode that subsequent treatment of the electrode with a surfactant improves the storage life and wetting properties of the electrode. See col. 30, l. 56 through col. 31, l. 8 and fig. 22 and 23. Said subsequent treatment of the electrode with surfactant would read on the specified "overcoating" giving the claim language its broadest reasonable interpretation. It would have been obvious to one of

ordinary skill in the art at the time the invention was being made to utilize the teaching of Maley for the electrode of Schlereth in order to improve the storage life and wetting properties of the electrode.

23. With respect to claim 19 (those limitations not covered above), Schlereth utilizes the electrode to obtain a measurement of phenothiazine or NADH. See section 1 or 3.1. This would read on the claimed "obtain a measurement indicative of a presence of an analyte in the sample".

Response to Arguments

24. Applicant's arguments filed 7-13-2005 have been fully considered but they are not persuasive. Applicant urges that there is no motivation for adding a surfactant as taught by Maley to the electrodes of Allen. In particular, applicant urges that Maley is drawn to the difficulty with a membrane during dry storage where the membrane becomes increasingly difficult to wetup. The membranes themselves are post-treated with a surfactant. The examiner will not dispute this discussion, but the passage the examiner was explicitly relying on (example X) was discussing the addition of surfactant to the electrode itself. Maley found that this also improved wetup of the sensor. The earlier examples address the advantages of adding surfactant to the membrane as well. In fact, Maley appears to summarize the discussion of example X by stating that it is advantageous to add surfactant to *all* the various layers of the electrode when they state "[t]he addition of the surfactant to the PAC, active and inactive layers, aids in sensor wetup" (col. 31, ll. 4-6).

25. Applicant also urges that the mixing of surfactant with the electrode material is not an overcoating. The examiner disagrees. Mixing the surfactant in with the powdered electrode

material would result in surfactant coating not only between all the particles of the electrode, but also a coating over the top of the electrode. The portion of the surfactant on the top of the electrode reads on applicant's broadly defined "overcoating". Moreover, Maley also suggest adding surfactant to other layers on the electrode (col. 31, ll. 4-6) to facilitate electrode wetup. The sulfur containing moieties of Allen are layers deposited onto its electrode surface. Moreover, the electrodes of Allen are presumably solid gold discs. See p. 72, l. 12. Hence any mixing of the electrode material of Allen (i.e. the solid gold disc) with a surfactant (as taught by Maley) would result in an overcoating of surfactant on the electrode of Allen.

26. Applicant also urges that there is no motivation for adding an overcoating of surfactant to the electrode of Allen. This is not persuasive. Surfactants by definition are wetting agents and their use as a wetting agent finds widespread utility for the purpose of facilitating the wetting up of devices desiring suitable wetup. Maley teaches that it was known to add wetting agents to the electrodes and all layers on the electrode to facilitate electrode wetup. Allen also requires suitable wet up of their electrode because, like Maley, they are drawn to electrochemistry being performed at the electrode-solution interface.

27. Applicant's remaining arguments about Maley appear to be drawn to a overly narrow reading of Maley that the surfactant is solely drawn to the addition of surfactant to the membrane. As the examiner discussed above, Maley teaches adding surfactant to the electrode itself as well as to all layers covering the electrode itself for the purpose of facilitating wetup (see discussion above).

28. With respect to the rejection of Schlereth and Maley, applicant urges that Maley is drawn to a different device, having a different structure and adapted to investigate a different analyte.

However, the purpose of the surfactant of Maley is for improving the wetup of the electrode itself and doesn't appear to involve the electrochemistry of the electrode. The role of the surfactant in Maley is tangential to the electochemistry being monitored by the other constituents of the electrode and it is unclear why this surfactant teaching would not find relevance for other electrodes like those of Schlereth. Applicant provides no specific reason why the electrode of Schlereth would not have been able to incorporate the surfactant of Maley. Moreover, the instant invention appears to evidences against this argument. In particular, this invention deals with a large class of sulfur containing coatings having widely varying structures and chemistries (see claims 2-17 as examples) combined with an overcoating of surfactant. Applicant gave no evidence that the choice of surfactant interacted with these various coatings in any distinctive manner. If the surfactant of the instant invention is applicable to the set forth wide range of coating materials of the instant invention, then the surfactant teaching of Maley should be applicable to the electrode structure of Schlereth.

Conclusion

29. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
September 20, 2005

KAJ K. OLSEN
PRIMARY EXAMINER